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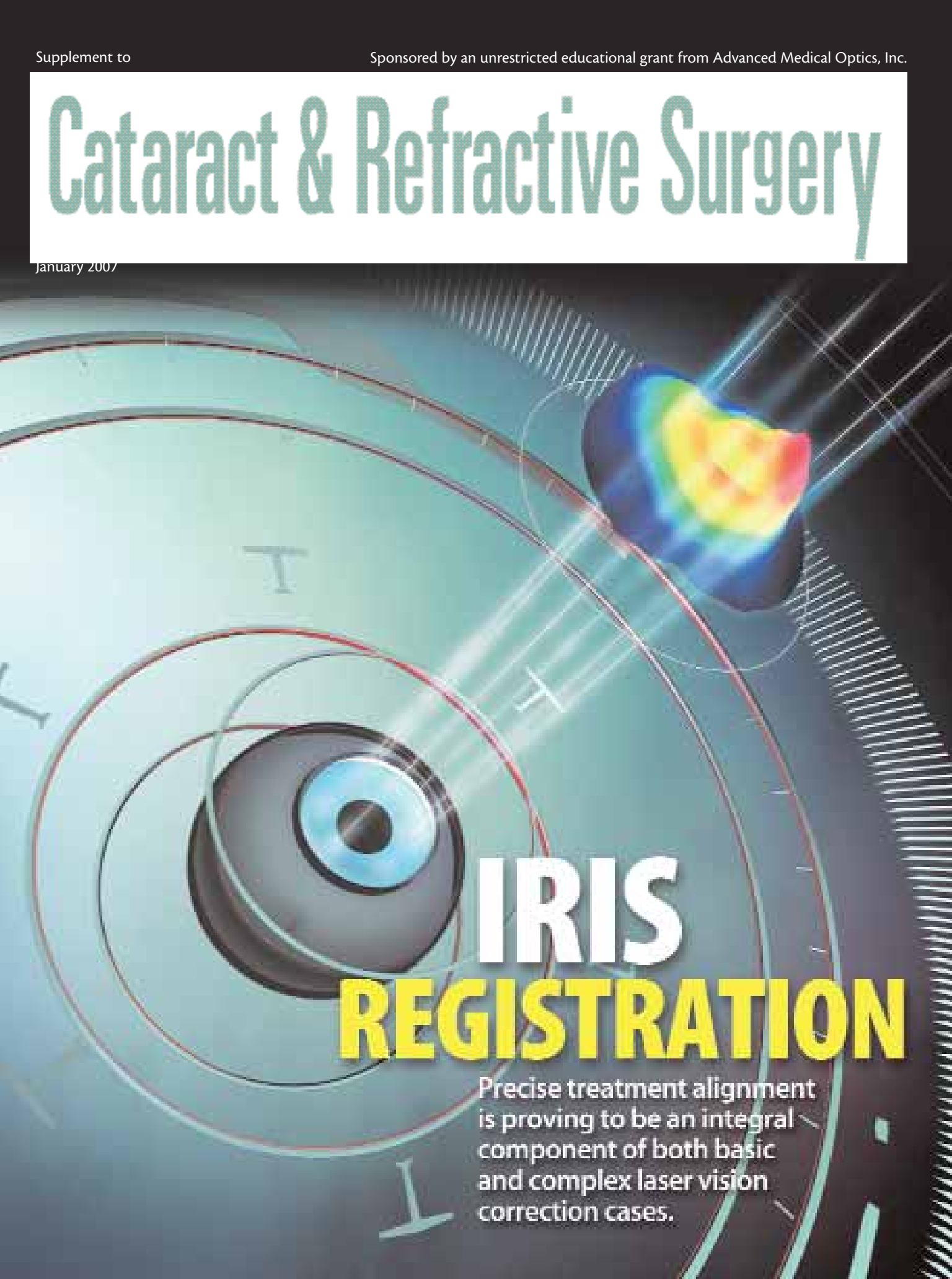

IRIS REGISTRATION

Precise treatment alignment is proving to be an integral component of both basic and complex laser vision correction cases.

Advancing the Science of Wavefront-Guided Ablations

BY DOUGLAS D. KOCH, MD

The first PRK procedure on a human eye was performed 20 years ago this year. Since then, refractive surgeons have witnessed rapid developments in excimer laser technology that have culminated in wavefront-guided procedures that allow us to offer patients excellent outcomes with rapid visual recovery and few complications.

In fact, wavefront technology has had such an obvious and dramatic impact on refractive surgery that it can be difficult to document discrete improvements from other, more nuanced technologies introduced since then, the most recent of which is iris registration (IR; Advanced Medical Optics, Inc., Santa Ana, CA). Registering the wavefront treatment to the iris increases the likelihood that the ablation will match the treatment plan derived from the preoperative wavefront, in terms of both torsional positioning and pupil centroid.

Initially, most of us believed that correcting cyclorotational misalignment was the most important component of IR. However, theoretical studies that my colleagues and I have done at Baylor have shown that for most patients, correcting pupil centroid shift actually has a bigger impact on quality of vision than the cyclorotational correction. In patients with ≥ 2.00D of astigmatism, the two components of IR are of equal importance.

IR is not a panacea, but it does provide another tool for improving quality of vision. Those of us who analyze our pre- and post-IR results are finding that our visual acuity outcomes are better and our rates of enhancements are lower with IR. These benefits translate into better patient care, higher patient satisfaction, less time that the surgeon has to handle patient problems, and higher patient referrals.

> Proficiency with IR is vital, particularly since all lasers will have some form of registration system in the near future.

Certainly, we would expect IR to be particularly valuable for patients who have greater amounts of astigmatism or higher-order aberrations or for those for whom cylinder and higher-order aberrations account for a greater percentage of the treatment. However, I think the data clearly indicate that all patients should benefit from a more precisely registered treatment. I would certainly want IR if I were undergoing surgery on my own eyes, and I do everything possible to capture in all my patients, because I believe IR offers them the best opportunity for the highest quality of vision.

Fortunately, most surgeons with IR today are able to successfully capture about 90% or more of their patients. Some are capturing nearly 100%. Proficiency with IR is vital, particularly since all lasers will have some form of registration system in the near future. In fact, I suspect that within 4 or 5 years, refractive surgeons will not be doing any laser surgery without IR.

In this special supplement to *Cataract & Refractive Surgery Today*, my colleagues and I explore the role of IR in the ongoing evolution of laser vision correction technology.

Lanny B. Hale, MD; Edward E. Manche, MD; and David M. Schneider, MD, join me in a roundtable discussion

about our experience with IR. Like me, these surgeons have all been using IR for more than 1 year, since shortly after the technology was introduced, and we all believe that IR is an important building block in optimizing our laser vision correction results. We offer pearls for improving capture rates at both the WaveScan (Advanced Medical Optics, Inc.) and laser and for dealing with special circumstances, such as retreatments or capturing in the presence of opaque bubbles produced by the IntraLase FS femtosecond laser (IntraLase Corp., Irvine, CA).

In addition, several authors take an in-depth look at important issues with IR. Edward Manche, MD, discusses his experience with retreatments using IR. Kerry Solomon, MD, shares some data from a study he has conducted comparing the results in treatments with and without IR. Finally, Richard L. Lindstrom, MD, shares his insights into the financial impact on a practice of reducing the need for enhancements through technological advancements such as IR.

As I have noted, IR will facilitate other technology improvements going forward. Colman R. Kraff, MD, addresses just this issue in his article on presbyopic multifocal ablations, which are even more dependent on precise registration than other laser treatments. ■

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Contents

Iris Registration: Pearls and Highlights

Four surgeons, each with at least 1 year of experience with IR, explain how the technology benefits their patients and share pearls for maximizing success with IR.


LANNY B. HALE, MD


DOUGLAS D. KOCH, MD


EDWARD E. MANCHE, MD


DAVID M. SCHNEIDER, MD

What is your current capture rate with iris registration?

Dr. Manche: My current capture rate is approximately 99% when I do PRK and about 80% for LASIK with the IntraLase FS femtosecond laser (IntraLase Corp., Irvine, CA). In LASIK cases, I am able to capture about 85% of brown eyes and only about 75% of blue eyes. I think this rate is a reasonable tradeoff between accuracy and the sensitivity of the machine. I would rather have some patients I cannot capture than a higher capture rate but lesser accuracy with iris registration (IR; Advanced Medical Optics, Inc., Santa Ana, CA).

Dr. Koch: My staff and I also have a higher capture rate for surface ablation than for LASIK with the IntraLase FS femtosecond laser. Overall, my capture rate is about 90%.

Dr. Hale: With some time and experience, my capture rate is now at approximately 99% with a microkeratome and about 95% with the IntraLase FS laser. I use two VISX lasers (Advanced Medical Optics, Inc.), one in my Wisconsin clinic and one in Arizona. Although both lasers have Advanced CustomVue with Iris Registration, one has a faster capture rate than the other. A major factor in increasing one's capture rate is simply improving the quality of the VISX WaveScan imaging (Advanced Medical Optics, Inc.). If the WaveScan photos are not good, you will not be able to get IR capture at the laser.

Dr. Schneider: My current capture rate is 99%. I have gotten to the point where it is highly unusual that I am not able to capture a patient.

What types of patients are the most challenging to capture with IR, and why?

Dr. Koch: My staff and I capture pretty much every brown or hazel eye, but the paler, more featureless blue irides can sometimes elude capture, especially in LASIK cases. Since we no longer perform LASIK with a mechanical microkeratome, it is hard to say whether the lower capture rate in LASIK cases is related to the IntraLase system or simply to lifting the flap.

Dr. Hale: Although it makes sense to me that light blue eyes would be harder to read or match, I have not personally found ease of capture to be related to eye color. I think the biggest stumbling block to capturing an eye can be pupil size. Anything that gives a relatively large disparity between the WaveScan pupil and the laser pupil is going to make it harder to capture. Deep-set eyes can be challenging because the light enters them from oblique angles, creating shadows that can interfere with the tracker or with IR.

Dr. Schneider: For me, the most challenging patients are those who have very narrow fissures or deep-set eyes who are also light-sensitive or otherwise prone to squeezing or squinting their eyes. Patients who have had previous RK or IOL implants, particularly multifocal IOLs, can also be challenging, because it is more difficult to obtain the wavefront images on which IR depends.

Dr. Manche: You do need a few seconds of good fixation to get IR capture. If the patient is "twitchy" or has saccadic eye movements during the capture phase, you are likely to have trouble capturing.

What do you do if IR will not engage?

Dr. Hale: I start with increasing or decreasing the illumination. At the beginning of every case, I typically ask what the size of the WaveScan pupil was. If it was small, I might turn the lights up a little to mimic that preoperative pupil. If the patient had a really large pupil, I know I'm going to need to keep the laser room very dark. My staff and I are very careful with head positioning and centration in every case, but I might also re-check the head's and eye's positions if there is any problem engaging IR.

Dr. Koch: After three or four tries, I simply proceed with the case without IR. If the patient has more than 2.00D of astigmatism, I will mark the corneas.

Dr. Schneider: Before surgery, I examine the patient at the slit lamp and review his preoperative exam data to make sure the WaveScan exams are of good quality. When I place the patient under the laser, I try to capture right away, before I make any cuts or marks. Doing so tells me how easy or difficult IR capture is going to be and gives me an early warning that I may need to make some lighting or head adjustments. If I cannot capture before I make the flap, I know I am not going to be able to capture afterward, so I will sometimes take the patient back to the WaveScan to repeat the imaging. These challenging cases are obviously a little more time consuming, but I feel the benefits of IR are worth the time spent trying to capture (Table 1).

How many times do you try to engage IR before moving on?

Dr. Manche: I will try three times. There are some cases, at least in my hands, where I just cannot capture. One has to balance the value of IR against the risk of corneal dehydration when attempting to capture for too long.

Dr. Hale: I agree. There is a point at which delaying any longer is worse than proceeding without IR. My team's LASIK nomograms are dependent on attention to detail, including maintaining consistent stromal hydration. Once the flap is up, the eye starts to dry out, and you will not get a consistent treatment effect if you leave the bed exposed for too long. I will typically try to capture three or four times in relatively quick succession. If it is a really complex treatment or an eye with high astigmatism, I might make five or six attempts, but that is rare.

Dr. Schneider: I am extremely persistent. I know engaging IR is possible, since I was able to do it before lifting the flap, and so I will persist until I get it.

Are you comfortable performing laser vision correction today without IR engaged?

Dr. Schneider: My staff and I have reviewed our data comparing pre- and post-IR outcomes. The visual acuity results from customized treatments with manual marking are good. If we have to treat based on manual marking, we know that it works, because we have a long history of doing it that way. However, I feel that IR is better if you can get it.

Dr. Manche: IR has raised the bar, but the results of customized ablation without it are still good. Once I have created a flap, failure to engage IR is not enough for me to cancel the case.

Dr. Hale: I am comfortable treating without IR, but I always feel like it is a slight failure if I am not able to get IR to engage. I think IR is a valuable part of the system, and I want the optimal technology for every patient. I still mark every eye with alignment dots. If I did not mark, I would be much more concerned about treating without IR.

Do you capture before or after lifting the flap?

Dr. Hale: I always capture after I lift the flap. The eye can move, or the patient may adjust his head a little during the flap lift.

Dr. Koch: Similar to what Dr. Schneider described earlier, I capture every patient before I remove the epithelium or before I lift the flap in the IntraLase patients. This approach allows me to determine the parameters, such as lighting and head position, required for capture. It also gives me time to make adjustments in a leisurely way without worrying about the stroma's drying out and altering the ablation parameters. I turn IR off while I lift the flap or remove the epithelium, then I re-engage it just before treating.

By turning IR off after the initial capture, there is of course the risk that I will not be able to capture after lifting the flap or removing the epithelium. However, there are data that suggest that the eye rotates when you remove the epithelium or lift a flap. Pupil size might also change as the result of the manipulation of the eye in making the flap or removing the epithelium.

TABLE 1. PEARLS FOR IR CAPTURE

- Pre-treat dry eye
- Patient's eye should be aligned directly under the laser
- Match pupil size under the laser with WaveScan pupil size
- Rotate/reposition patient's head as needed
- Avoid obscuring IR cameras with hands or instruments
- Focus on the operating microscope on the stroma

> "Our capture rate is 99%. We have gotten to the point where not being able to capture a patient is highly unusual."
>
> —David M. Schneider, MD

What pearls can you share for improving capture rates at the WaveScan?

Dr. Hale: Like most people, my staff and I used to turn off all the lights during the WaveScan exam to make the room as dark as possible. Now, I think a better approach is to get the pupil as close to 7.0mm as possible for the purposes of WaveScan and IR capture. Achieving that pupillary size usually means keeping the room very dark as we have always been advised, but there are people with naturally large pupils that need to be made smaller. We have dimmer controls on our lights now, so the technician can adjust them up or down as needed.

I also think it is important for the technicians to take ownership of the quality of their scans, because if the WaveScan is bad, there is no chance of capturing at the laser. Finally, we help patients relax their accommodation by telling them not to read in the waiting room and, if possible, not to spend the whole day at the computer before they come in for their exam.

Dr. Koch: Dryness, more than anything else, causes problems with obtaining good Hartmann-Shack images and therefore problems with IR capture at the WaveScan. My staff and I are sticklers for treating dry eye proactively. Before measuring or treating with wavefront, I want the ocular surface to be sufficiently moist without epithelial defects, punctate erosion, or other signs of dry eye.

Dr. Schneider: If we have a very anxious patient who is having trouble relaxing accommodation, we will give him some Valium (Hoffmann-La Roche Inc., Nutley, NJ) to help him relax. We also play soft background music in the WaveScan room. If there is any difficulty, I will personally go in the WaveScan room with the patient. Sometimes, they just respond better when the doctor is in the room.

What pearls can you share for improving capture rates at the laser?

Dr. Koch: Try to position the patient so that the eye is directly under the laser. If the patient is looking at the fixation light at an angle, the iris will have a bit of obliquity that makes it more difficult for the cameras to capture. Again, a healthy, moist surface is helpful. Lighting is probably the biggest factor in maximizing your IR capture. You need to adjust the lights at the laser so that the patient's pupil size more or less matches what it was at the WaveScan. For me, the most common setting is the ring light on one click as the only illumination. If the pupil is still too small with this low-light setting, I first focus on the corneal surface with the ring light on, then I turn off the ring light and give the eye a few seconds to equilibrate before performing the IR capture with no illumination at all.

Dr. Manche: You definitely have to play around with illumination. If the laser's coaxial and indirect lights are turned up too high, your capture rate will fall dramatically. Instead, aim to have the room's illumination as dim as possible. Sometimes, if the chin is tipped up or the patient has a prominent bridge, you may need to rotate the head a little to capture. In general, you need very good exposure, so it is important to make sure you do not have a Weck cell sponge or a drape in the field that is obscuring the cameras. It is possible for something to interfere with IR even if it is not interfering with the infrared tracking cameras (Figures 1 and 2).

Dr. Hale: Head positioning and alignment is absolutely critical. The eye must be perfectly parallel to the ground, which can be challenging in some patients. The OR staff who work with you must understand how to get the patient's pillow positioned just right. Finally, you have to have good focus on the stroma for the IR cameras to focus. On very rare occasions, I have adjusted the focus down a little bit to get IR capture in a very deep-set eye, but that is certainly not a common adjustment.

Marking the eye is also very helpful. I still mark every eye with alignment dots. One limitation with IR is that, if the

IR Capture Under the Laser

Shadows

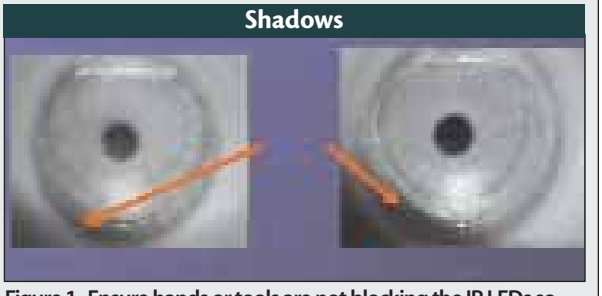

Figure 1. Ensure hands or tools are not blocking the IR LEDs so enough light is available for the cameras to pick up the iris detail.

Obscured Outer Iris Boundary

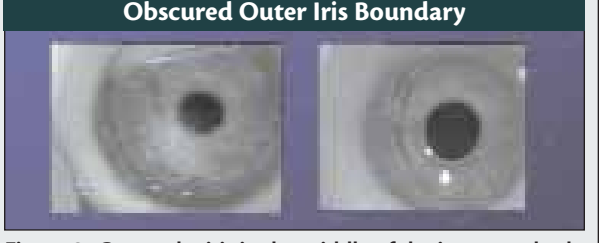

Figure 2. Center the iris in the middle of the interpapebral fissure to ensure the outer iris boundary is not cut off.

eye rotates too much (more than 10º in either direction), IR will not engage, but the laser does not give you a message stating why this happened. Manual marking, although not as precise as IR, should at least get you within the 10º range so that IR can engage. Of course, manual marking is also a fallback for the rare case in which IR will not engage.

All of you use the IntraLase FS laser. What pearls can you offer for dealing with the opaque bubble layer (OBL) in capturing at the excimer laser?

Dr. Hale: Many people who use the IntraLase FS laser in combination with the VISX laser have the machines in the same room and swivel the patient between them. However, I have mine in separate rooms. Patients normally sit for a 10- to 15-minute "intermission" between the time I create the flap and actually lift it under the excimer laser. This waiting period lets the bubbles dissipate, which may improve my capture rate, although that is not why I chose to structure the procedure this way. On the other hand, I think there are a lot of physicians getting very high capture rates even with both lasers in the same room, so I am not convinced that the OBL is a major problem.

Dr. Koch: I am not sure that there is a clear relationship between the OBL and the system's ability to pick up iris detail. I typically push the bubbles out of the way. If I have significant OBL in the right eye, I will treat the left eye first in order to let the bubbles in the other eye dissipate. However, the OBL is rarely a problem when capturing, in my experience.

Dr. Manche: I don't think IntraLase flaps make much of a difference in terms of one's IR capture rate. I do think the act of lifting any sort of flap makes capture more challenging, because the lamellar bed is not as clear and pristine a surface as you have with surface ablation.

Which is more important, cyclorotational compensation or compensation for pupil centroid shift?

Dr. Manche: They are both very important. The cyclotorsional component is critical in the correction of cylinder. The pupil centroid compensation can have a greater impact in terms of night vision complaints and how effectively the treatment corrects higher-order aberrations.

Dr. Koch: My staff and I studied this question in a series of 58 eyes of 38 patients.[1] We evaluated the actual amount of cyclorotation and centroid shift for each eye, then calculated from their wavefront maps the residual higher-order aberrations that would be present had the compensation for rotation or centroid shift not occurred. The mean cyclorotational error was 2.5º, with some eyes rotating as much as 8.7º. The mean centroid shift was 0.29mm, with a range of up to 0.50mm (Figure 3).

For all lower- and higher-order aberrations except astigmatism, correcting pupil centroid shift had a bigger impact on quality of vision than did correcting for cyclotorsion (Figure 4). The only exception was in patients with ≥ 2.00D of astigmatism, where both components of IR were comparable in importance. This finding was a bit surprising, since we expected cyclotorsion to be the more important feature. We learned that an error in the centration of the laser ablation induces coma at levels that can be fairly significant in terms of the modulation transfer function and Strehl ratios.

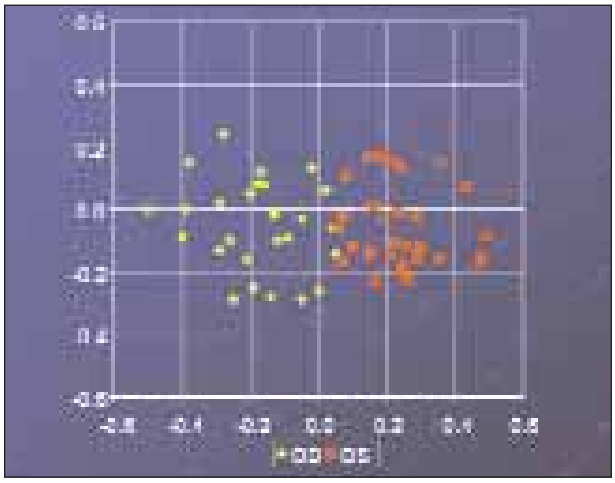

Figure 3. The mean centroid shift was 0.29mm, with a range up to 0.50mm.

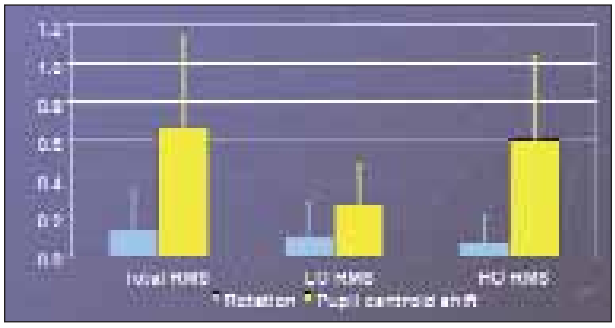

Figure 4. Higher-order aberration pupil centroid shift resulted in significantly more induction of RMS error than cyclotorsional rotation (*P*<.001).

Dr. Schneider: Although cyclotorsion has received more attention, pupil centroid compensation makes a lot of sense to me. If you are going to all the trouble to take a WaveScan map and deliver a customized treatment to the eye, it seems logical to make sure it is centered over the pupil in the same way you took the measurements.

What type of patients will most benefit from registering the laser ablation to the wavefront map?

Dr. Manche: Personally, I have been most impressed with the impact of IR in cases of high cylinder. In the past, if I treated a high astigmat, I would expect to be left with some

residual astigmatism and to need to enhance that patient 3 to 6 months later. With IR, we are commonly seeing these patients with absolutely no cylinder postoperatively. It is really quite impressive. IR is also critical in retreatments with complex, asymmetrical ablations.

Dr. Hale: I agree. The more unusual the laser ablation pattern, the more important it is to get it lined up properly. Typically, higher-order aberrations represent about 5% of the total correction, but they can be as much as 30% to 50% of the total correction in complex retreatment cases.

Dr. Schneider: Another group for which IR is important is patients with very large pupils. A patient with a large pupil and an off-center treatment is going to experience glare, halo, and reduced visual contrast at night. One of the benefits of Advanced CustomVue with IR is that it is able to reduce these types of side effects. Most patients actually report that their night vision is better after treatment than it was preoperatively.

Dr. Koch: The data show that everybody will benefit from IR. I think those who benefit the most are high astigmats and patients whose treatments feature a higher percentage of small spots, which would include eyes with greater amounts of higher-order aberrations or irregular astigmatism as well as hyperopes, perhaps. In a simple, straightforward myopic treatment, the ablation pattern consists primarily of larger-spot diameters. IR may not be quite as significant in these cases, but it should matter to some degree in everybody.

Do you consider the registration of cyclotorsion and centroid shift as a standard in today's laser vision correction environment?

Dr. Hale: It's my standard. I do 100% customized, wavefront-guided surgery, and I perform 100% of my cases with IR if I can capture. I am a big believer in the benefits of these technologies.

ENHANCEMENT RATE: A KEY TO PATIENT SATISFACTION, PRACTICE SUCCESS

Refining primary treatment precision reduces enhancement rates, saving time and money for the refractive practice.

BY RICHARD L. LINDSTROM, MD

From a patient perspective, avoiding the hassle, expense, and risk of an enhancement is clearly beneficial. The more likely we are to achieve a 20/20 outcome with the primary treatment, the more likely it is that patient satisfaction and referrals for laser vision correction will increase. In addition, reducing one's enhancement rate has more quantifiable financial benefits for a practice.

At Minnesota Eye Consultants, my colleagues and I have calculated that an enhancement costs our practice about $750 per eye when all the associated costs, including the laser, materials, surgeon time, staff time, etc., are factored in (Table 1).

TABLE 1. ENHANCEMENT COST

Conventional surgery:
1000 cases x 10% = 100 enhancements x $750 each = $75,000

CustomVue with IR:
1000 cases x 5% = 50 enhancements x $750 each = $37,500

SAVINGS TO PRACTICE = $37,500

When we first started performing laser refractive surgery 10 to 12 years ago, our enhancement rate was close to 20%. Over the years, as the lasers advanced, that rate came down to about 10% with standard ablation. Today, with the current Visx CustomVue system (Advanced Medical Optics, Inc., Santa Ana, CA), we have been able to reduce our enhancement rate to just under 5%.

The economic impact of a 50% cut in enhancements is significant. If you are performing 1,000 laser vision correction cases per year and can cut your enhancement rate by half, from 10% to 5%, the savings to the practice is nearly $40,000 per year.

Enhancements have gone down because we have seen about a 10% to 12% increase in the number of 20/20 outcomes as well as a 10-fold reduction in the number of patients with significant night vision complaints.

Overall, advanced CustomVue has reduced our enhancement rate by 50% and improved our enhancement success rate by 10% or more. We now use Advanced CustomVue with IR whenever possible, because it improves the chance of the best possible outcome for the patient and makes sense economically for the practice. ■

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Dr. Koch: I view it as another building block to optimizing the results that we get with laser vision correction.

Dr. Schneider: IR is absolutely standard in my practice. I would almost say that I have become psychologically dependent on it. I feel much more secure and comfortable when I know IR is locked on and registered, because it gives me added confidence that I am treating the correct eye of the correct patient and that I am going to give him the best possible result. When customized ablations came out, people initially thought it was a lot of hype, but the data have proved otherwise. I think the same will be true for IR. There are improvements still to be made, such as the active tracking of rotation and pupillary shift during treatment, but this is the starting point from which the technology will move forward.

How has the addition of IR affected your retreatment rates?

Dr. Manche: This is where the extra expense and effort of IR really pays off. My practice's overall enhancement rate is not significantly lower, but retreatments of high-cylinder (>2.50D) patients have gone down dramatically, from 10% to 15% previously to about 5% with IR.

Dr. Koch: My overall enhancement rate dropped from 8.4% to approximately 7.4% with IR. Although that is not a huge decrease, it occurred during the period when we also added high-myopic treatments, which might have been expected to increase retreatments. Similarly, our standard deviation of 0.36D for a myopic CustomVue LASIK procedure result remained steady, despite going from an upper limit of -6.88D to -10.00D or higher. By all rights, the standard deviation in our outcomes should have increased with the greater range of treatments.

Dr. Schneider: My practice's retreatment rate with IR is extremely low, around 2%. We have had only 12 enhancements in the first 1,100 eyes treated with IR, and while there may still be more enhancements to come in that group, we certainly know we are getting an excellent effect from the initial treatment. Moreover, when an enhancement is necessary, we are getting better results than previously. A customized wavefront correction, tested with a PreVue lens (Advanced Medical Optics, Inc.) and registered with IR, gives me much greater confidence in treating symptomatic patients after an otherwise successful primary treatment.

How has the addition of IR affected patient satisfaction with laser vision correction in your practice?

Dr. Hale: It is hard to quantify the exact contribution of any one technology. We have seen a steady improvement in patient-satisfaction rates as the quality of vision with laser vision correction keeps getting better.

Dr. Manche: I go back to the question of enhancements. Patients always regard the need for a second procedure as a failure of sorts, no matter how far they have come from their original refraction. The fewer retreatments you have, the happier your patient population is.

> "Custom laser systems, even with excellent trackers, can still produce subtly decentered treatments if they don't account for pupil centroid shift when the pupil enlarges. IR is the only technology that can compensate for that."
>
> **—Lanny B. Hale, MD**

Dr. Schneider: I think patient satisfaction is affected not only by the impact on outcomes, but also just by the concept of IR. People have seen iris recognition technology in the movies and perceive it as a high-tech advancement. Patients feel very comfortable knowing that we have a similar technology to register the laser treatment to the images we use to measure their eyes. ■

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1. Koch DD. Cyclorotational rotation registration versus pupil centroid shift compensation: which is the more significant clinical improvement? Paper presented at: The ASCRS/ASOA Annual Meeting; March 19, 2006; San Francisco, CA.

The Impact of Iris Registration on Laser Vision Correction Outcomes

A retrospective comparison shows clinically significant differences in eyes treated with IR versus traditional CustomVue.

BY KERRY D. SOLOMON, MD

There is no question that wavefront-guided ablations provide advantages over conventional treatments in terms of quantity and quality of vision. I believe that if refractive surgeons are going to take wavefront-guided correction to the next level, we really need to talk about registration. We know the eye moves and changes slightly between the wavefront measurement and the laser treatment. The real trick is to match up exactly where we are measuring with where we are treating.

Iris Registration (IR; Advanced Medical Optics, Inc., Santa Ana, CA) matches distinctive iris features in both images, allowing us to overlie the wavefront maps and precisely place our laser spots where they need to be in order to hit our refractive target.

TESTING IR

IR sounds nice in theory, but until recently, we have not fully understood whether there is any clinical significance to using this type of registration system. At Medical University of South Carolina, my colleagues and I retrospectively analyzed 3-month results from two groups of myopic patients.

The first group (n=33) underwent CustomVue treatments (Advanced Medical Optics, Inc.) without IR. The second group (n=86) had Advanced CustomVue with IR. The mean MRSE was -2.95D in the non-IR group and -3.90D in the IR group. The age of the patients and range of refractive error was pretty similar in both groups.

When we looked at the attempted versus achieved correction, we saw that both groups performed quite well. However, the IR patients were more likely to be within 0.50D of their intended corrections. The correlation coefficient for this group was almost perfect, 0.99. There were a few outliers in the non-IR group, but none in the group treated with IR.

What is most noticeable is that 40% of patients in the IR group were seeing 20/15 or better postoperatively, compared to less than 10% of the non-IR group.

We might expect IR to produce a better astigmatic correction. In fact, in our comparison, it did. In the non-IR group, there was a 53% reduction in cylinder from pre- to postoperative measures, compared with a 75% reduction in cylinder with IR (Figure 1).

UCVA was very good in both groups, as we have come to expect from wavefront-guided ablation, but the IR group fared significantly better than the non-IR patients at every visual acuity point (Figure 2). What is most noticeable is that 40% of patients in the IR group were seeing 20/15 or better postoperatively, compared to less than 10% of the non-IR group.

Comparing postoperative UCVA to preoperative BCVA, about 35% to 40% of the IR group gained at least one line of vision. This means that, without glasses, 40% of the time patients are seeing better after surgery than their best-corrected vision before surgery, which is wonderful. In the group without IR, less than 10% achieved this kind of a gain. To me, these results speaks volumes about the impact of registration on outcomes.

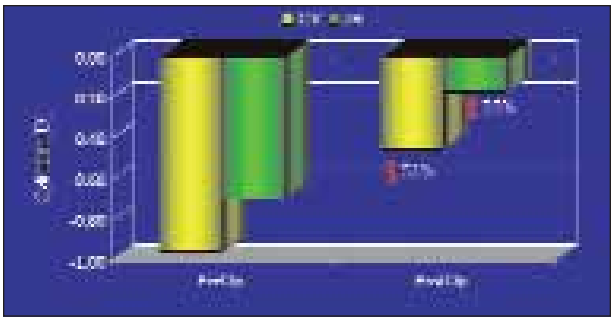

Figure 1. In our comparison of two groups of myopic patients, the group that received IR achieved better astigmatic correction with a 75% reduction in cylinder from pre- to postoperative measures compared to the non-IR group with a 53% reduction.

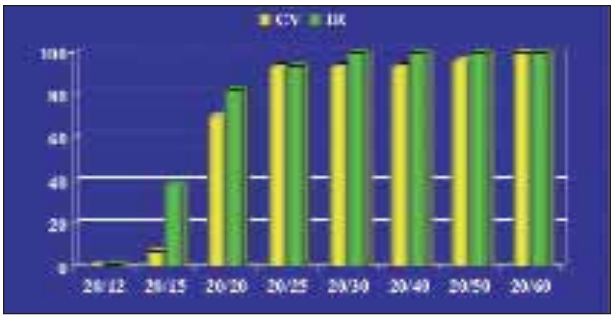

Figure 2. The IR group achieved significantly better UCVAs than the non-IR group at every visual acuity point.

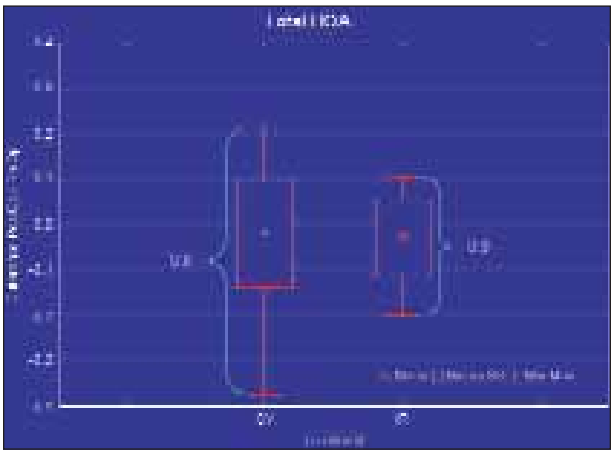

Figure 3. The standard deviation and range of induction of higher-order aberrations was significantly less in the IR group.

QUALITY OF VISION

As we all know, Snellen visual acuity certainly does not tell the full story of a patient's visual performance. How about quality of vision with IR versus without registration? To assess quality of vision, we looked at the induction of total higher-order aberrations, spherical aberration, horizontal and vertical coma, and secondary astigmatism. We found that the mean induction in higher-order aberrations, for total aberrations and for the individual aberrations, was about the same in both groups. However, the standard deviation and range of induction of higher-order aberrations was much greater in the non-IR group (Figure 3). In the group that received IR, there was a reduction by about half in the spread of induced higher-order aberrations. Those results are significantly better than what we see with CustomVue without IR, which is already leaps and bounds ahead of conventional ablations.

One might ask why does the addition of IR result in these improvements in acuity and quality of vision? The first reason is that IR compensates for cyclotorsion. Several studies have identified a 3º to 10º cyclorotation when a patient moves from a sitting position, as they would be at the WaveScan, to supine, as they are under the laser. In our database of treatments with IR, the mean cyclotorsion was 3.7º ± 2.3º, and it was as high as 9.1º in some eyes. Sixty percent rotated counter-clockwise; the other 40%, clockwise. Cyclotorsion is certainly *a* factor in the differences between our two groups, but I do not believe it is *the* major factor.

The major difference in the visual performance between the two groups is probably the IR system's compensation for pupil centroid shift. This refers to the movement of the center of the pupil in a dilated patient compared to the center of the pupil in that same patient with a more constricted pupil. It turns out that the overall centroid shift is more significant than we once thought. In our clinic's IR database, the mean horizontal shift, usually nasal, was 250 ± 135µm. The mean vertical shift, usually superior, was 211 ± 123µm. In some eyes, the centroid shifts were as large as 500µm. Clearly, treatments applied without IR compensation are going to be slightly decentered in some eyes and will prevent an optimal outcome.

IR, by taking into account both cyclotorsion and pupil centroid shift, allows us to more precisely align the treatment with the wavefront map. The end result is improved visual outcomes, better accuracy of treatment, less induction of higher-order aberrations, and overall, a better quality of vision, which is what all of us are aiming for in wavefront-guided laser vision correction. ■

Dr. Solomon is Professor of Ophthalmology at the Storm Eye Institute and Medical Director of Magill Laser Center, both at the Medical University of South Carolina in Charleston. He is not a consultant for Advanced Medical Optics, Inc., and he acknowledged no direct financial interest in the company or its products. Dr. Solomon may be reached at (843) 792-8854; solomonk@musc.edu.

Retreatments With Fourier Algorithms and Iris Registration

Complex cases demand careful screening, the best possible wavefront technology, and precise registration.

BY EDWARD E. MANCHE, MD

I have been very interested in developments that improve refractive surgeons' ability to treat patients with poor outcomes from previous refractive surgery. Fortunately, today's lasers produce excellent results with far fewer complications. Nevertheless, we all have patients who have undergone previous RK or experienced decentered ablations or other problems from prior refractive surgery that have left them with less-than-optimal results. Solving these refractive problems can be a huge relief—for both patient and surgeon.

STUDYING LASER SYSTEMS' ALGORITHMS

At Stanford, my colleagues and I conducted a series of randomized, prospective studies comparing Fourier-based treatments to Zernike-based treatments. We looked first at naturally occurring myopia in primary eyes and found that we had significantly better outcomes in the Fourier group. Next, we looked at Fourier versus Zernike in retreatments. Again, we found better outcomes in the Fourier group, with a significantly higher percentage of eyes in that group seeing 20/20 or better, 20/12.5 or better, and even 20/10 (Figure 1). There was better predictability in the Fourier group, as well.

When Iris Registration (IR; Advanced Medical Optics, Inc., Santa Ana, CA) is added to Fourier analysis, we have yet another level of precision in positioning the treatment on the eye.

ROUTINE ENHANCEMENTS

My colleagues and I retrospectively analyzed the results of 120 eyes of 102 patients with simple residual myopia following previous LASIK or PRK. All eyes underwent LASIK retreatment with Fourier algorithms and IR. The results in these routine enhancements were excellent. All eyes were

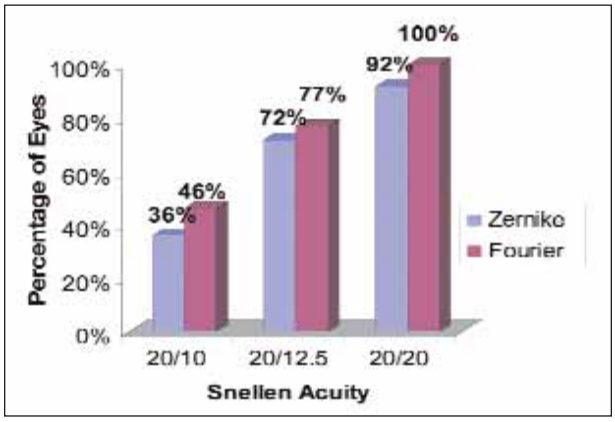

Figure 1. A significantly higher percentage of eyes achieved 20/20 or better, 20/12.5 or better, and even 20/10 or better vision with a Fourier-based versus a Zernike-based wavefront-guided ablation.

20/30 or better uncorrected at 1 and 3 months, almost all were 20/20, and about three-quarters could actually see 20/15 or better without spectacles. (Figure 2). Predictability was also very high. We demonstrated a decrease in total higher-order RMS in this group of patients, as well as statistically significant decreases in coma and trefoil. There were no changes noted in spherical aberration.

Routine residual myopia cases without significant visual symptoms have been successfully treated in the past. The more interesting cases, of course, are retreatments in highly aberrated eyes. These patients present with a diverse range of problems, including decentrations, steep central islands, or other nonuniform ablations, thin stromal beds, corneal scarring, small-diameter ablations, and flap striae. This is a much more difficult group to treat, and it warrants careful examination and diagnosis of the underlying problem.

DECENTRATIONS

Generally speaking, the best cases for wavefront-guided ablation are those in which the decentration is small in magnitude (< 1.5 to 2.0mm) and the initial ablation was shallow (< 4.00 to 5.00D).

My staff and I treated a 55-year-old man who had undergone conventional LASIK 4 years earlier for compound hyperopic astigmatism. He had residual refractive error, but his main complaint was of poor quality of vision, specifically ghosting in the left eye, which did not improve with spectacles. Computerized corneal topography showed a slight inferior decentration in the left eye, which also had significant levels of higher-order aberration, especially coma.

The patient underwent a LASIK re-treatment using a Fourier-based algorithm and IR. At 6 months postoperatively, his UCVA had improved from 20/40 to 20/16, his manifest refraction was nearly plano (+0.25 +0.25 X 75), and his total higher-order aberrations had been reduced by more than half. The patient's coma went from 0.34µm preoperatively to 0.04µm postoperatively. His trefoil and spherical aberration were nearly eliminated, as well. His postoperative topography shows better centration of the central steepening. Most importantly for the patient, he experienced a complete resolution of his ghosting and night vision issues.

POST-RADIAL KERATOTOMY

Patients who have undergone previous RK and have residual refractive error or quality-of-vision complaints can be very difficult to treat. I no longer perform LASIK in these eyes, given the potential risks of opening the old keratotomy incisions. Wavefront-guided surface ablation can be quite effective in well-chosen cases in which you are able to obtain good wavefront examinations. My staff and I perform PRK and use topical mitomycin C to prevent haze.

I treated a 35-year-old patient who underwent RK approximately 15 years ago. Since that time, she had suffered poor quality of vision during the day and especially at night. She was very dissatisfied with glasses and soft contact lenses and unable to wear rigid gas permeable lenses. Her UCVA was 20/200 with a refraction of -2.75 +0.75 X 18 OS, and her BCVA was only 20/30.

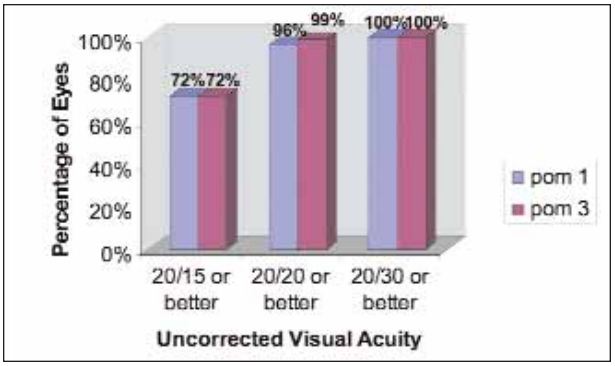

Figure 2. At 1 and 3 months post-enhancement, almost all eyes were 20/20 or better, and about three-quarters could actually see 20/15 or better without spectacles.

> "We have found that Fourier-based treatment algorithms with IR work extremely well for routine as well as complex retreatments."

This patient's original RK treatment was a well-centered, classic eight-incision RK with the incisions extending out to the limbus. My staff and I were able to get good wavefront and IR capture on this patient. Her total higher-order aberration was 0.68µm, with relatively high levels of trefoil and spherical aberration.

The outcome was very good in this particular case. Nine months postoperatively, the patient's UCVA and BCVA both had improved to 20/20 in the treated eye. There was a decrease in total higher-order RMS values, coma was reduced by half, and computerized topography revealed a much more regular cornea. The patient's refractive error was completely eliminated, as were her night vision problems. This young patient was thrilled to be able to resume driving at night.

CONCLUSIONS

We have found that Fourier-based treatment algorithms with IR work extremely well for routine as well as complex retreatments.

Many highly-aberrated eyes are not candidates for wavefront-guided retreatment, so careful patient selection and diagnostic evaluation is mandatory. We have a low threshold to switch from LASIK to surface ablation, particularly in cases of previous RK or insufficient corneal tissue. Complex treatments with even very small refractive errors can require the removal of a significant amount of tissue, as seen in the case above. High-quality, reproducible wavefront images are absolutely necessary in order to treat with confidence.

If all these hurdles can be overcome, Fourier technology with IR provides greater precision in complex treatments, improves outcomes, and allows a wider range of treatments than was possible with previous laser technologies.

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Laying the Groundwork for Future Treatments

Accurately registering laser treatments to the iris is even more important for aspheric ablations than for monofocal ablations.

BY COLMAN R. KRAFF, MD

The FDA investigational team for the multifocal Advanced CustomVue ablation (Advanced Medical Optics, Inc., Santa Ana, CA) has recently concluded a small US investigational study of wavefront-guided aspheric ablations in hyperopic presbyopes.

The multifocal Advanced CustomVue ablation differs from a standard hyperopic correction in that a subtle ablation shape change is made to the patient's wavefront map using variable spot scanning (VSS) technology (Advanced Medical Optics, Inc.). The treatment makes the curvature of the eye more aspheric to allow for near vision in the center of the cornea that blends into distance vision in the periphery.

In addition to expanding the patient's range of vision with the curvature change, the Advanced CustomVue software creates a wavefront-guided correction that considers the individual's specific higher-order aberrations. It further customizes the treatment by taking into account the patient's pupil dynamics and size. For a patient with large pupils, increasing the central near zone to fully encompass the reading pupil will have the best results.

This treatment provides what I consider omnifocal vision for hyperopic presbyopes. It balances and optimizes the optics throughout the entire range of vision to provide a longer depth of focus and a wider depth of field. The result is that patients can see well at all distances, including near, far, and intermediate, under a variety of lighting conditions.

THE ROLE OF IR

The presbyopia study is among the first to incorporate Advanced CustomVue iris registration (IR) technology (Advanced Medical Optics, Inc.), which I believe is critical to successfully treating presbyopes.

My IR capture rate has improved to about 95% since IR was first introduced. My practice's technicians have also gotten better at taking the WaveScan so that they now produce better quality images in which IR can more easily identify and match iris markers. Learning how to adjust lighting conditions as necessary is another important factor in successfully engaging IR at the laser.

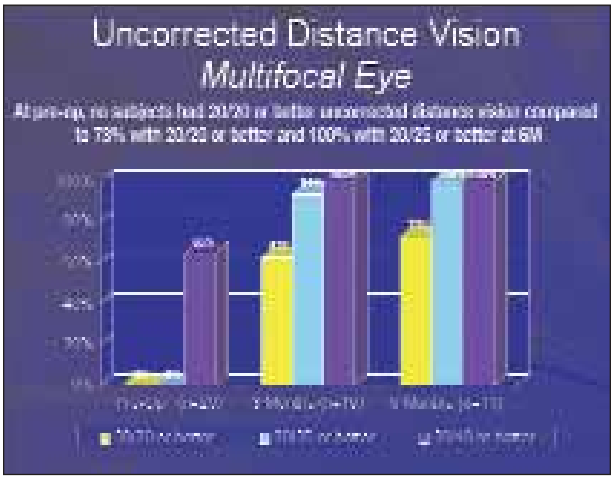

Figure 1. At 6 months postoperatively, 73% of patients showed 20/20 UCVA at distance in the aspheric eye, with all patients seeing at least 20/25.

IR ensures that the wavefront pattern ablated at the time of surgery corresponds precisely to the patient's preoperative wavefront map. This is partly accomplished by compensating for any cyclotorsion that occurs between the measurement and treatment. For any patient, compensating for cyclotorsion should provide crisper vision through the better correction of cylinder and higher-order aberrations.

In aspheric presbyopic ablations, IR becomes even more important, because the treatment size and location are dependent upon the pupil's size and centroid. The change in curvature that provides the near vision enhancement must be delivered directly over the center of the entrance pupil. The pupil centroid can shift as the pupil changes size. Without IR to identify and compensate for any shifts that occur, it is impossible to know whether the presbyopic treatment is accurately centered.

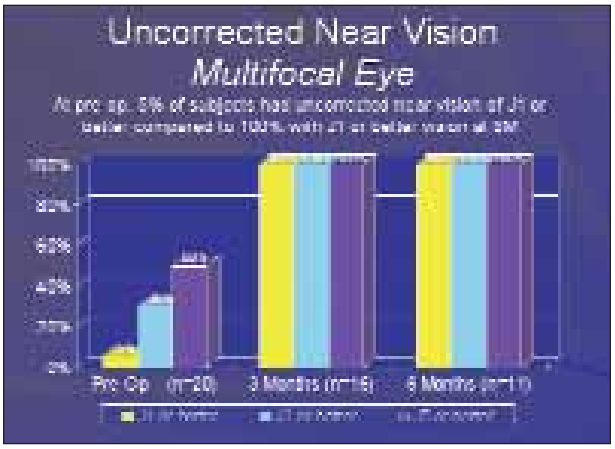

Figure 2. Postoperatively, 100% of patients were J1 or better in the aspheric eye at 6 months and showed excellent near vision results.

US STUDY RESULTS

In the investigational study, we treated 20 subjects with aspheric ablations in their nondominant eyes. We targeted the dominant eyes for emmetropia with a normal CustomVue hyperopic correction.

The patients in the study are an average of 46.7 years old (range, 41 to 57 years) and predominantly male (70%). In the aspheric eyes, the mean preoperative sphere was +1.50D (+0.25 to +2.50D), with minimal cylinder (mean, 0.30D; range, 0 to 1.00D). Thus far, 3-month follow-up is available on 16 subjects, 11 have reached the 6-month mark, and eight have reached 9 months.

Preoperatively, no patient had distance or intermediate UCVA of 20/20 or better. Six months postoperatively, 73% of the patients were seeing 20/20 at distance in their aspheric eye, and all saw at least 20/25 (Figure 1). Binocularly, 100% of patients had 20/20 distance UCVA. We saw similar results for intermediate UCVA.

The patients' near vision improvements were dramatic as well. Preoperatively, only 5% of subjects could see J1 uncorrected. Postoperatively, 100% of patients saw J1 or better in their aspheric eye at 6 months (Figure 2), and this outcome held true when they were tested binocularly.

Patients were more satisfied with their UCVAs at both distance and near postoperatively than they had been with their BCVA before surgery.

CANADIAN RESULTS

W. Bruce Jackson, MD, and colleagues in Ottawa, Canada, have been involved in a larger-scale study of presbyopic ablations, with data on many patients now available out to 12 months. They are treating both eyes of the subjects, which we would expect to be more effective in reducing dependence on spectacles.

Dr. Jackson's team has reported excellent visual acuity results. At 1 year, 100% of the subjects achieved a UCVA of both 20/25 or better for distance and J3 or better for near. Eighty-five percent were seeing at least 20/25 and J1 simultaneously.

The patients had high rates of satisfaction with night vision, which we have also seen in the US study and indicates that contrast sensitivity is not adversely affected. In fact, the Canadian data show that while the treatment somewhat reduces contrast sensitivity, patients experience improvement in this category throughout the postoperative period. At 12 months, contrast sensitivity is well within normal values for 50- to 75-year-olds.

The investigators also found that higher-order aberrations are stable following the treatment. Coma, for example, which many expected would increase, went up only slightly and then remained stable. Spherical aberration shifted from positive to negative, as would be expected from the creation of an aspheric, more prolate cornea. This effect also remained stable throughout the postoperative period.

> "In aspheric presbyopic ablations, IR becomes even more important, because the treatment size and location are dependent upon the pupil's size and centroid."

One very interesting feature of the Canadian study is that the eyes treated after IR was introduced ended up a little closer to emmetropia and had slightly better near acuity than those treated without IR.

In the US study, I would expect to see even better results when we begin enrolling patients in a larger clinical trial and can treat both eyes with an aspheric correction as has been done in Canada. This approach should give patients an even broader, truly omnifocal range of vision.

To prepare for the addition of wavefront-guided presbyopic corrections, practitioners will need to become proficient with IR. The technology is something I prefer to use in all treatments, but it is absolutely essential to obtaining optimal results in presbyopic corrections. ■

Colman R. Kraff, MD, is in private practice at the Kraff Eye Institute in Chicago, and he is a clinical instructor at Chicago's Northwestern University Medical School. He is not a consultant to Advanced Medical Optics, Inc., and acknowledges no financial interest in the company or its products. Dr. Kraff may be reached at (312) 444-1111; ckraff@kraffeye.com.

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